



USSN: 10,772,058

Applicant: SCHRIER *et al.*

Attorney Docket: I-2000.537 US D1

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 00020304 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 3<sup>rd</sup> February 2000

PJ Packer

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No. FS33819

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

AKZO NOBEL NV  
VELPERWEG 76  
6824 BM  
THE NETHERLANDSNAME AND ADDRESS  
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:  R2	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  00020304
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by:	
<input checked="" type="checkbox"/> A scientific description	
<input type="checkbox"/> A proposed taxonomic designation	
(Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 3 <sup>rd</sup> February 2000 (date of the original deposit) <sup>1</sup>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
IV. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr P J Packer	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):
Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Date: <i>PJ Packer</i> 31/3/02

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

AKZO NOBEL NV  
VELPERWEG 76  
6824 BM  
THE NETHERLANDSVIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: AKZO NOBEL NV  Address: VELPERWEG 76 6824 BM THE NETHERLANDS	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  00020304  Date of the deposit or of the transfer: 3 <sup>rd</sup> February 2000
II. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <sup>2</sup> . On that date, the said microorganism was <div style="display: flex; flex-direction: column; align-items: flex-start;"> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <input checked="" type="checkbox"/> <sup>3</sup> <div style="margin-left: 10px;">viable</div> </div> <div style="display: flex; align-items: center;"> <input type="checkbox"/> <sup>3</sup> <div style="margin-left: 10px;">no longer viable</div> </div> </div>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>		
<p>R2 - 00020304</p> <p>CELLS WERE COUNTED ACCORDING TO THE TRYPAN BLUE DYE EXCLUSION METHOD.</p>		
V. INTERNATIONAL DEPOSITARY AUTHORITY		
Name:	Dr P J Packer ECACC CAMR	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):
Address:	Porton Down Salisbury Wiltshire SP4 0JG	
		Date: <i>PJ Packer 31/3/00</i>

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

## Certificate of Analysis

**Product Description** R2  
**Accession Number** 00020304

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**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 14/02/00

**Result:**

Viable Cell Count:	3.9 x 10 <sup>6</sup> cells/ml
Percentage Viability:	70%
Confluent within:	2 days
Overall Result:	PASS

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**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.  
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

**Test Number:** 20612

**Date:** 13/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

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Authorised by.....*P. J. Paul*.....ECACC, Head of Quality...*27/3/00* Date

## Certificate of Analysis

**Product Description** R2  
**Accession Number** 00020304

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**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20612

**Date:** 13/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

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**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:** 20612

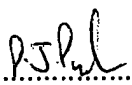
**Date:** 13/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

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\*\*\* End of Certificate \*\*\*

Authorised by..........ECACC, Head of Quality.....27/3/00 Date